Patient Information Leaflet - Australia

THE iFUSE IMPLANT SYSTEM®

The iFuse Implant System® is a set of implants and associated surgical instruments. The implants are designed for permanent placement in the body. The system includes iFuse 3D™ and iFuse TORQ™ implants and associated instruments. Implants are made from a titanium alloy and are produced by 3D printing.

iFuse 3D

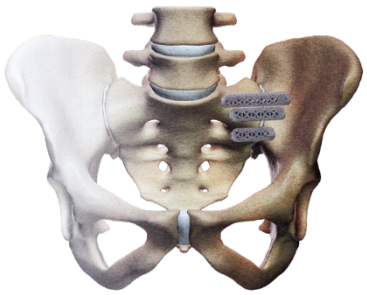
iFuse TORQ

INTENDED PURPOSE

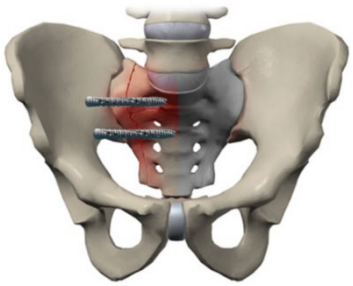
The intended purpose of iFuse 3D is SI joint fusion. The intended purpose of iFuse TORQ is both SI joint fusion and pelvic fracture fixation.

In **SI joint fusion**, two or more implants are placed through the ilium, or wing bone of the pelvis, across the SI joint, and into the sacrum, the large bone at the base of the spine. Placing multiple implants immediately reduces motion of the joint. The implants are also designed to promote long-term fusion of the joint. Sacroiliac joint fusion means that the joint no longer moves and that the sacrum and the ilium are permanently joined together. Reducing joint motion is a common approach to alleviating pain related to joint degeneration (e.g., from arthritis) or joint disruption (from trauma). Studies have shown that iFuse implants placed across the SI joint reduce pain and disability related pain caused by SI joint dysfunction and improve quality of life in most cases.

iFuse TORQ is also used for **fracture fixation**. One or more iFuse TORQ implants are placed across the fracture to stabilize it. Fracture stabilization using a screw is a common orthopedic procedure. Stabilizing a fracture reduces pain and allows for bone healing. iFuse TORQ implants are placed with the end of the implant in the middle of the sacrum.



Pelvis Treated for SI Joint Dysfunction with iFuse 3D Implants



Pelvis Treated for Sacral Fracture with iFuse TORQ Implants

WHAT TYPE OF PATIENT IS THE iFUSE IMPLANT SYSTEM INTENDED TO TREAT?

The iFuse Implant System is intended for two types of patients:

1. Patients with pain related to **SI joint dysfunction**. This pain can occur in the buttocks, groin, and hip, and may radiate down the leg.

2. Patients with **pelvic fractures**. Pelvic fractures can be due to high energy trauma (e.g., a car accident) or low energy trauma (a fall at home).

INDICATIONS FOR USE

*For **iFuse 3D**:* The iFuse Implant System is intended for sacroiliac joint fusion including use in high and low energy fractures of the pelvic ring.

*For **iFuse TORQ**:* The iFuse TORQ Implant System is intended for sacroiliac joint fusion and fracture fixation, including use in high and low energy fractures of the pelvic ring.

PATIENT OPERATING INSTRUCTIONS FOR USE OF THE iFUSE IMPLANT SYSTEM

Once implanted, there are no post-operative operating instructions for the iFuse Implant System. It is important to develop and follow an appropriate post-operative rehabilitation plan with your surgeon and other healthcare providers, such as your physical therapist.

INTENDED PERFORMANCE OF THE iFUSE IMPLANT SYSTEM

iFuse implants are designed for permanent implantation in the body without breakage or migration after placement.

POTENTIAL RISKS & SIDE EFFECTS

As with all surgeries, the risks associated with the iFuse Procedure include, but are not limited to:

- Adverse reactions to anesthesia
- Hemorrhaging or bleeding which is difficult to control and may become dangerous
- Muscle and/or nerve damage
- Localized bruising or swelling
- Dangerous blood clots
- Wound site infections, wound re-opening and damage to the tissues surrounding the surgical site
- Excessive radiation exposure
- Lung damage
- Death

Risks specific to the iFuse Procedure include, but are not limited to:

- Local injury to the pelvis
- Increased pain in the sacroiliac joint or surrounding tissues and joints
- Allergic reaction to or rejection of the implants
- Migration, loosening, breakage or failure of the implant
- Muscle pain due to the change in function of the SI joint
- Stress to and fracture of the bones in the pelvis surrounding the implants
- Need for additional surgery to remove or adjust the positioning of one or more implants

INTERACTION WITH OTHER EQUIPMENT

Patients who have had the iFuse Procedure can likely still undergo magnetic resonance imaging but should notify their healthcare providers prior to doing so as the imaging procedure needs to be performed in certain ways to adjust for the implants. Other metallic implants should not be placed in close proximity to iFuse implants as they could cause iFuse implant breakage.

iFUSE IMPLANT SYSTEM MAINTENANCE & PERFORMANCE

The iFuse Procedure is designed to last a patient's lifetime and no maintenance is required. Any increased pain in the SI joint or surrounding tissues and joints following surgery should be evaluated with your doctor.

iFUSE IMPLANT SYSTEM MATERIALS & MANUFACTURING

The iFuse 3D and iFuse TORQ implants are constructed using an additive manufacturing process using an implant grade titanium alloy powder known as Ti-6Al-4V ELI. The 3D printing process is intended to create a titanium implant with a porous surface that mimics human cancellous bone.

Patients who are allergic to certain metals, have tumors or active infections in or around the sacroiliac joint should not be treated with iFuse. Since iFuse 3D is not intended for fracture fixation, patients with certain types of fractures of the pelvis should have those fractures treated first, prior to treatment with iFuse 3D implants. iFuse TORQ implants may be used for treating fractures.

SERIOUS ADVERSE INCIDENT REPORTING

If you experience any serious adverse incidents as a direct result of the iFuse Implant System, contact the Therapeutic Goods Administration using the following website address www.tga.gov.au